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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,038	08/09/2001	Hisatomi Ito	NANP110US	4720

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AMIN & TUROCY, LLP  
1900 EAST 9TH STREET, NATIONAL CITY CENTER  
24TH FLOOR,  
CLEVELAND, OH 44114

EXAMINER
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DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/927,038

Applicant(s)

ITO ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,5,11,12,14 and 15 is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8 and 13 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Detailed Action***

1. Claims 1, 2, 6, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wenzel et al., US 2001/0046963 A1.
2. Claims 1, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Castillo et al., US 2001/0047032 A1.
3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanzendorfer et al., 6,423,747.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Amendment***

The following is responsive to Applicant's amendment received March 24, 2003.

No claims are cancelled. No new claims are added. Claims 1-15 are currently pending.

The previous claim rejection under 35 USC 112, paragraph 1, set forth on pages 2-4 of the office action mailed Dec. 18, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(e), set forth in paragraph 2 of the office action mailed Dec. 18, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) set forth in paragraph 5 of the office action mailed Dec. 18, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claim 13 under 35 USC 103(a) over the JP 8-81382 reference, set forth in paragraph 8 of the office action mailed Dec. 18, 2002 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the rejection of claims 1, 2, 6, 7 under 35 U.S.C. 102(e) over Wenzel et al., US 2001/0046963 A1; the rejection of claims 1, 6 under 35 U.S.C. 102(e) over Castillo et al., US 2001/0047032 A1; and the previous rejection of claim 13 under 35 U.S.C. 103(a) over Lanzendorfer et al., 6,423,747; have been considered but are not found to be persuasive. These rejections can be found at paragraphs 1,3-4 and 6-8 of the office action mailed Dec. 18, 2002.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Dec. 18, 2002 with the following additional comment:

- ***The rejection of claims 1, 2, 6, 7 under 35 U.S.C. 102(e) over Wenzel et al., US 2001/0046963 A1:***

It is Applicant's position that Wenzel et al. is not available as prior art under 102(e) because the effective filing date of the patent publication is Feb. 14, 2001, whereas the instant application has priority, under 35 USC 119, to August 17, 2000. Applicant has submitted a certified English translation of the Japanese priority document thus perfecting priority back to August 17, 2000.

However, the Examiner respectfully submits that the Wenzel patent application publication has priority back to the provisional application, which provides support for the information disclosed in the patent application publication. This provisional

was filed Feb. 25, 2000 which precedes the priority date of the instant application.

Therefore, the rejection is respectfully maintained.

▪ ***The rejection of claims 1, 6 under 35 U.S.C. 102(e) over Castillo et al., US 2001/0047032 A1:***

It is Applicant's position that Castillo et al. is not available as prior art under 102(e) because the effective filing date of the patent publication is Dec. 26, 2000, whereas the instant application has priority, under 35 USC 119, to August 17, 2000. Applicant has submitted a certified English translation of the Japanese priority document thus perfecting priority back to August 17, 2000.

However, the Examiner respectfully submits that the Catillo patent application publication has priority back to the provisional application, which provides support for the information disclosed in the patent application publication. This provisional was filed Dec. 30, 1999 which precedes the priority date of the instant application. Therefore, the rejection is respectfully maintained.

▪ ***The rejection of claim 13 under 35 U.S.C. 103(a) over Lanzendorfer et al., 6,423,747;***

It is essentially Applicant's position that Lanzendorfer et al. do not disclose nor do they fairly suggest the claimed method. Specifically, Applicant argues that Lanzendorfer et al. do not disclose that citrus extracts containing flavonoids have an effect on extending neuritis. Instead, Lanzendorfer et al. teach that flavonoids in combination with cinnamic acid derivatives are useful for treating "stinging" sensations on the skin due to their antioxidative effects. One of ordinary skill in

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the art, at the time the invention was made, would not have been motivated to use the disclosed flavonoid-containing extract for extending neurites based on the teachings of Lanzendorfer et al.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully submits that Lanzendorfer et al. disclose Applicant's invention as currently claimed. Applicant argues that Lanzendorfer does not disclose that citrus extracts containing flavonoids are effective in extending neuritis. However, please note that claim 13 allows for contacting neurocytes with any amount of composition containing polyalkoxyflavonoids, not just an amount effective to extend neurites. Furthermore, Applicant has not clearly argued how neurite growth would not be obvious in the method of Lanzendorfer when a substantially identical composition is being administered to an area of the body, i.e. skin, which is known to be equipped with marker cell neurite complexes.

Applicant also attempts to further distinguish the claimed method from the method disclosed in Lanzendorfer by arguing that the flavonoids are administered in combination with cinnamic acid derivatives; however, please note that Applicant's claim recites "comprising" language. According to MPEP 2111.03, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are

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essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In this case, because claim 13 recites "comprising" language, it does not exclude the additional cinnamic acid derivative component of the composition disclosed in Lanzendorfer.

It is for these reasons that the rejection is maintained.

***New Ground(s) of Rejection***

***Claim Rejection – 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 8, 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "the composition comprising 'a polyalkoxyflavonoid' extract from a plant belonging to the citrus family" does not appear to have adequate support in the specification as originally filed. It is respectfully submitted that this limitation is broader than what was originally disclosed in

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the specification. Throughout the specification, Applicant describes the citrus abstract as containing a polyalkoxyflavonoid compound represented by Formula (1) and more specifically Formulae (2) and (3). (Please see page 5, lines 16-18; page 7, lines 8-9; page 12, lines 12-15). The specification does not, however, support the new limitation, which would cover other polyalkoxyflavonoid compounds, within the citrus family, having a structure other than those represented by Formula (1). Therefore, because the newly added limitation appears to be broader than what was originally disclosed in the specification, it is deemed new matter.

### ***Conclusion***

Claims 1-3, 6-8, 13 stand rejected.

Claims 9-10 are objected to as being dependent upon a rejected base claim.

Claims 4, 5, 11, 12, 14, 15 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

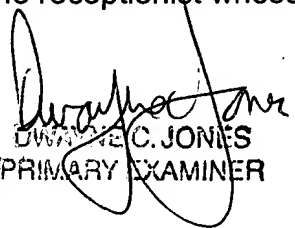
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM



August 7, 2003



DWAYNE C. JONES  
PRIMARY EXAMINER